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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,585	01/13/2006	Robert S. Foote	DC0261US.NP	1514
26259 7590 07/10/2008 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER				
COUNTS, GARY W				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
07/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary

Application No.

10/553,585

Applicant(s)

FOOTE ET AL.

Examiner

GARY W. COUNTS

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed April 28, 2008 is acknowledged and has been entered.
Currently claim 4 is pending and under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Zoghbi et al (US 2004/0243010).

Zoghbi et al disclose determining the level of BNP in samples obtained from a patient. Zoghbi et al disclose determining the level of BNP in a sample from the patient prior to exercise to establish a baseline (control) and also teaches determining the level of BNP in a sample from the patient post exercise (abstract, pgs 9-10, particularly p. 10, Example 7). Zoghbi et al disclose that levels of BNP increased from baseline to post-exercise. Zoghbi et al disclose that the exercise stress test can be performed with myocardial perfusion imaging wherein a dual isotope, rest-stress protocol is used (p. 6, para. 0070).

Regarding the interpretive "wherein" clause recited in claim 1 ("wherein an increase in the level in the sample as compared to the control is indicative of cardiac ischemia in the individual ", the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results to those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See *Texas Instruments, Inc. v. International Trade Comm.*, 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also *Minton v. National Assoc. of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1641

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 2003/0109420) in view of DeVito (US 5,249,124).

Valkirs et al disclose a method of diagnosing myocardial ischemia in a patient. (pages 39-40). Valkirs et al disclose determining a level of B-type natriuretic peptide (BNP) in a sample isolated from a patient (p. 7, pgs 31-32 & 39-40). Valkirs et al disclose that the sample can be obtained after the induction of a stress test (p. 39 1st col). Valkirs et al disclose comparing the level to a control and correlating the result to myocardial ischemia. Valkirs et al disclose that the control is obtained prior to stress testing (p. 39, 2nd col). Valkirs et al disclose that when the test sample is greater than the control that a diagnosis of myocardial ischemia is made.

Valkirs et al differs from the instant invention in failing to teach subjecting the patient with an exercise stress test with myocardial perfusion imaging wherein a dual isotope, rest-stress protocol is used.

DeVito discloses a stress test with myocardial perfusion studies wherein dual isotope, rest-stress protocol is used. DeVito teaches that dual-isotope study produces two images of the patient's heart and the relationship between the images shows where heart muscle is affected by arteriosclerosis and where it is infarcted (col 2, lines 21-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a stress test with myocardial perfusion studies as taught by DeVito into the method of Valkirs et al because Valkirs et al is generic with respect to the stress test and DeVito teaches that such studies provides two images of the patient's heart and the relationship between the images shows where heart muscle is affected by arteriosclerosis and where it is infarcted.

Regarding the interpretive "wherein" clause recited in claim1 ("wherein an increase in the level in the sample as compared to the control is indicative of cardiac ischemia in the individual ", the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results to those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See *Texas Instruments, Inc. v. International Trade Comm.*, 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim.").

See also *Minton v. National Assoc. of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Response to Arguments

7. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/

Examiner, Art Unit 1641

/Long V Le/

Supervisory Patent Examiner, Art Unit 1641